

EPOGEN

A review of the FDA database found that 1329 AE reports have been received for Epogen as of 3/27/97. Of these 20 are for the age group 0-9 and 35 are for ages 10-19. While the total reports have a slight female predominance, for the 0-9 group 12/19 are male and 22/34 are male for the 10-19 age group. 94% of the total reports were submitted via the manufacturer. Two of the <19 reports were not submitted by the manufacturer..

The 10 most frequent COSTART terms for the reports as a whole are:

hypertension	143
convulsion	113
pruritis	108
pain,injection site	88
headache	87
rash	85
thrombosis	75
fever	58
urticaria	56
no drug effect	48

Other COSTARTS

flu-like syndrome	45
dyspnea	37
arthralgia	32
chills/fever	25
CVA	22
eosinophilia	22
myalgia	22
leukocytosis	21
hyperkalemia	20
diarrhea	19
thrombocythemia	11
tachycardia	10

The most common COSTARTS for the <19 group are very similar to the above list with the exception of "no drug effect" which is the third term on the <19 list with 4 reports. One report states the apparent lack of effect may be due to an underlying infection, and another says that the failure is probably due to cystine crystals in the bone marrow.